

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

| | | |
|--------------------------------|---|--------------------|
| VALIDUS PHARMACEUTICALS, INC., |) | |
| |) | |
| Plaintiff, |) | |
| |) | |
| v. |) | C.A. No. 08-36-GMS |
| |) | |
| ACTAVIS SOUTH ATLANTIC LLC, |) | |
| and ACTAVIS, INC., |) | |
| |) | |
| Defendants. |) | |

**ACTAVIS SOUTH ATLANTIC LLC'S AND ACTAVIS, INC.'S ANSWER, DEFENSES,
AND COUNTERCLAIMS TO VALIDUS PHARMACEUTICALS, INC.'S
COMPLAINT FOR PATENT INFRINGEMENT**

Defendants Actavis South Atlantic LLC and Actavis, Inc. (collectively "Actavis") file this, their Answer and Defenses to Plaintiff Validus Pharmaceuticals, Inc.'s ("Validus") Complaint for Patent Infringement. Actavis denies each and every allegation contained in the Complaint that is not expressly admitted below. Any factual allegation below is admitted only as to the specific admitted facts, not as to any purported conclusions, characterizations, implications or speculations that arguably follow from the admitted facts. Actavis denies that Plaintiffs are entitled to the relief requested or any other relief.

ANSWER

1. On information and belief, Actavis admits that Plaintiff Validus is a corporation organized and existing under the laws of the State of Delaware and has its principal place of business at 119 Cherry Hill Road, Suite 310, Parsippany, New Jersey 07054.
2. Admitted.
3. Actavis admits that Actavis, Inc. is a corporation organized and existing under the laws of the State of Delaware. Actavis admits that Actavis, Inc. does business in the State of Delaware. Actavis admits that Actavis, Inc. is the parent of Actavis South Atlantic LLC and that

Actavis South Atlantic LLC is a wholly-owned subsidiary of Actavis, Inc. Actavis denies the remaining allegations of paragraph 3. Actavis, Inc. has a principal place of business at 60 Columbia Road, Building B, Morristown, New Jersey 07960.

4. Actavis admits that it is in the business of manufacturing, distributing and selling pharmaceutical products. Actavis denies the remaining allegations of paragraph 4.

5. Denied.

6. Actavis admits that the Plaintiff's claims for patent infringement purport to arise under the patent laws of the United States, Title 35 of the United States Code, but denies that such claims have merit. Actavis admits that this Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. Admitted.

8. Admitted.

9. Admitted.

10. Actavis believes that the statute described in paragraph 10 speaks for itself and denies all allegations in paragraph 10 inconsistent with the cited statute.

11. Actavis believes that the statutes described in paragraph 11 speak for themselves and denies all allegations in paragraph 11 inconsistent with the cited statutes.

12. Actavis believes that the statute described in paragraph 12 speaks for itself and denies all allegations in paragraph 12 inconsistent with the cited statute.

13. Actavis believes that the statute described in paragraph 13 speaks for itself and denies all allegations in paragraph 13 inconsistent with the cited statute.

14. Actavis believes that the statute described in paragraph 14 speaks for itself and denies all allegations in paragraph 14 inconsistent with the cited statute.

15. On information and belief, admitted.

16. On information and belief, Actavis admits that pursuant to the FDA's approval, Validus currently markets carbamazepine extended-release capsules for the treatment of acute manic and mixed episodes associated with Bipolar I Disorder under the trademark EQUETRO®.

17. Admitted.

18. Actavis admits that by maintaining the listing of the '253 patent in the Orange Book, Validus represents that the '253 patent claims an approved method of using the drug product in NDA 21-710 upon which a claim of patent infringement could reasonably be asserted if a person not licensed by Validus engages in the manufacture, use, or sale of that drug. 21 U.S.C. § 355(b)(1)(G). Actavis admits that Actavis South Atlantic LLC and Actavis, Inc. have not filed with the FDA a dispute regarding the listing of the '253 patent in the Orange Book in connection with NDA No. 21-710. 21 C.F.R. § 314.94(a)(12)(vii). Actavis lacks knowledge sufficient to admit or deny the remaining allegations of paragraph 18, and therefore denies those allegations.

19. Actavis admits that on or before December 4, 2007, it submitted to the FDA an ANDA (ANDA No. 79-180) that included paragraph IV certifications under §505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic ACT ("FDCA"), for carbamazepine extended-release capsules which are the bioequivalent of Validus' Carbamazepine product sold under the brand name EQUETRO®. Actavis admits that it is seeking approval under §505(j) of the FDCA to engage in the commercial manufacture and sale of carbamazepine extended release capsules and that in its ANDA filing it certified, pursuant to §505(j)(2)(A)(vii)(IV) of the FDCA that the patents listed in the Orange Book in connection with NDA No. 21-710 were invalid and/or not infringed by Actavis' proposed carbamazepine

extended release capsule product. Actavis lacks knowledge sufficient to admit or deny the remaining allegations of paragraph 19, and therefore denies those allegations.

20. Admitted.

21. Actavis admits that ANDA No. 79-180 seeks approval for a proposed carbamazepine extended-release capsule to be used in the treatment of acute manic and mixed episodes associated with Bipolar I disorder. Actavis lacks sufficient knowledge to admit or deny the remaining allegations of paragraph 21 and therefore denies those allegations.

22. Actavis admits that ANDA No. 79-180 seeks approval for a proposed carbamazepine extended-release capsule to be used in the treatment of acute manic and mixed episodes associated with Bipolar I disorder. Actavis lacks sufficient knowledge to admit or deny the remaining allegations of paragraph 22 and therefore denies those allegations.

23. Actavis reasserts and incorporates by reference each of the answers to paragraphs 1 through 22 above, as if fully set forth herein.

24. Actavis admits that the '253 patent is titled "Methods For The Treatment of Bipolar Disorder Using Carbamazepine" and was issued by the United States Patent and Trademark Office on December 20, 2005. Actavis lacks sufficient knowledge to admit or deny the remaining allegations of paragraph 24 and therefore denies those allegations.

25. On information and belief, admitted.

26. On information and belief, Actavis admits that Validus currently markets a carbamazepine product in the United States, which it sells under the brand name EQUETRO. Actavis lacks sufficient knowledge to admit or deny the allegations of paragraph 26 and therefore denies those allegations.

27. Denied.

- 28. Denied.
- 29. Admitted.
- 30. Denied.
- 31. Denied.
- 32. Denied.

DEFENSES

33. Claims 1-34 of the '253 patent are invalid for failure to meet the requirements of patentability under 35 U.S.C. § 101 *et seq.*, including, without limitation §§ 101, 102, 103 and 112.

34. Actavis has not infringed, induced infringement or contributed to the infringement of any valid claim, if any, of the '253 patent, either literally or under the doctrine of equivalents.

35. Plaintiff is barred by 35 U.S.C. § 288 from recovering costs associated with this suit.

36. Actavis reserves the right to allege additional affirmative defenses as they become known throughout the course of discovery.

ACTAVIS' COUNTERCLAIM FOR DECLARATORY RELIEF

Without admitting any of the allegations of Validus' Complaint for Patent Infringement and Permanent Injunction other than those expressly admitted herein, and without prejudice to Actavis' right to plead additional counterclaims as the facts of the matter warrant, Actavis hereby asserts the following counterclaims against Plaintiff Validus:

Nature of the Action

1. This counterclaim seeks a declaratory judgment of invalidity of the '253 patent asserted by Plaintiff in the action. Actavis seeks judgment under the patent laws of the United

States, 35 U.S.C. § 101 *et seq.*, including, without limitation §§ 101, 102, 103 and 112 and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

Parties

2. Actavis South Atlantic LLC is a limited liability corporation organized and existing under the laws of the State of Delaware and has its principal place of business at 13800 N.W. 2nd Street, Suite 190, Sunrise, Florida 33325.

3. Actavis, Inc. is a corporation organized and existing under the laws of the State of Delaware and has its principal place of business at 60 Columbia Road, Building B, Morristown, New Jersey 07960.

4. On information and belief, Validus Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware and has a principal place of business at 119 Cherry Hill Road, Suite 310, Parsippany, New Jersey 07054.

Jurisdiction and Venue

5. This Court has subject matter jurisdiction over this counterclaim pursuant to 28 U.S.C. § 1331 and 1338(a), the patent laws of the United States set forth at 35 U.S.C. §§ 101 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

6. Personal jurisdiction over Validus is proper because, *inter alia*, Validus has consented to the personal jurisdiction of this Court by commencing their action for patent infringement in this judicial district, as set forth in Validus' complaint.

7. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b), (c) and 1400(b).

Count I

Declaratory Relief Regarding Invalidity

8. Actavis incorporates by reference paragraphs 1-7 of these counterclaims as though fully repeated here.

9. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*, Actavis requests a declaration of the Court that claims 1-34 of the '253 patent are invalid because they fail to satisfy the conditions for patentability specified in 35 U.S.C. § 101 *et seq.*, including, without limitation, sections 101, 102, 103, and/or 112.

Count II

Declaratory Relief Regarding Non-infringement

10. Actavis incorporates by reference paragraphs 1-9 of these counterclaims as though fully repeated here.

11. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*, Actavis requests a declaration of the Court that Actavis has not infringed, induced infringement or contributed to the infringement of any valid claim, if any, of the '253 patent, either literally or under the doctrine of equivalents.

Count III

Declaratory Relief Regarding Exceptional case

12. Actavis incorporates by reference paragraphs 1-9 of these counterclaims as though fully repeated here.

13. For having brought this action, Validus is liable under 35 U.S.C. § 285, making this case exceptional and Actavis seeks recovery of its attorney fees under that statute as part of this Counterclaim.

Prayer for Relief

WHEREFORE, Actavis respectfully requests that this Court enter judgment in Actavis' favor against Validus and issue an order:

- a. That claims 1-34 of the '253 patent are invalid;
- b. That Actavis has not infringed, induced infringement or contributed to the infringement of any valid claim, if any, of the '253 patent, either literally or under the doctrine of equivalents
- c. That Validus take nothing by their Complaint;
- d. Denying Validus' request for injunctive relief;
- e. Dismissing Validus' Complaint with prejudice;
- f. That this case is exceptional;
- g. Awarding costs and attorney fees to Actavis; and
- h. Awarding any other such relief as is just and proper.

POTTER ANDERSON & CORROON LLP

OF COUNSEL:

Roderick B. Williams
Tracey B. Davies
Stephen M. Hash
Reese P. McKnight
VINSON & ELKINS LLP
The Terrace 7
2801 Via Fortuna, Suite 100
Austin, TX 78746-7568
Tel: (512) 542-8400

By: /s/ Richard L. Horwitz
Richard L. Horwitz (#2246)
David E. Moore (#3983)
Hercules Plaza, 6th Floor
1313 N. Market Street
Wilmington, DE 19899
Tel: (302) 984-6000
rhorwitz@potteranderson.com
dmoore@potteranderson.com

Dated: February 6, 2008
846826 / 32688

*Attorneys for Defendants Actavis South
Atlantic LLC and Actavis Inc.*

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

CERTIFICATE OF SERVICE

I, Richard L. Horwitz, hereby certify that on February 6, 2008, the attached document was electronically filed with the Clerk of the Court using CM/ECF which will send notification to the registered attorney(s) of record that the document has been filed and is available for viewing and downloading.

I further certify that on February 6, 2008, the attached document was Electronically Mailed to the following person(s):

Jack B. Blumenfeld
Maryellen Noreika
Morris Nichols Arsht & Tunnell LLP
1201 North Market Street
Wilmington, DE 19899
jblumenfeld@mnat.com
mnoreika@mnat.com

George F. Pappas
Roderick R. McKelvie
Jeffrey B. Elikan
Steven P. Berman
Sarah J. Chikos
Covington & Burling LLP
1201 Pennsylvania Avenue, N.W.
Washington, D.C. 20004
gpappas@cov.com
rmckelvie@cov.com
jelikan@cov.com
sberman@cov.com
schikos@cov.com

/s/ Richard L. Horwitz
Richard L. Horwitz
David E. Moore
Potter Anderson & Corroon LLP
Hercules Plaza – Sixth Floor
1313 North Market Street
P.O. Box 951
Wilmington, DE 19899-0951
(302) 984-6000
rhhorwitz@potteranderson.com
dmoore@potteranderson.com